Its method is one of peer review, examination and comparison of data. Its standards of quality are based upon performance data and comparisons between institutions. The accreditation model has proved that over time it can actually raise standards by providing institutions with incentives to move to higher levels of quality. And when one thinks about it, there would seem to be no particular reason why the accreditation model could not be applied to quality of care and cost containment as well. But the point to be made here is that the methods that are coming into being to use patient care data to contain costs may not be all that different from the methods that are needed to develop and use patient care data to measure, assure and even improve quality—and even outcomes—in patient care, while at the same time relating quality, and possibly even outcomes, to costs.

The essential ingredients to measure and assure both quality and costs in patient care seem to be at hand. These include the basic integrity of the vast majority of physicians, the objective data bases that are now developing in every facet of patient care, and the experience with and general acceptance of peer review as a tool to assure quality. Thus it would seem that objective measures for both quality and costs can come from comparisons of objective data to be found in patient care data bases.

Elsewhere in this issue Howard Lang discusses the use of comparisons between services, DRGs, physician performance and the like in terms of costs. All that remains is to use similar or comparable comparisons to assess quality, and then to begin to find ways to relate these assessments of quality to the benefit obtained from the cost. Much of what is needed to do this is already accepted or in place. It is to be hoped that measures such as these comparisons of objective data can be developed and then adopted into general use so as to help meet the challenge of assuring patient care of good quality at affordable cost in these difficult but stimulating times.

MSMW

Clinical Application of Biological Research

THE SPECIALTY CONFERENCE, "Recombinant DNA in Medicine," elsewhere in this issue, describes numerous past and recent accomplishments aided by "recombinant DNA" technology and projects their impact on medicine. Although the rubric of "recombinant DNA" could be criticized ("modern biology" might be more appropriate), the introduction of this technology does provide a chronological marker of sorts for an infusion of excitement and rebirth into the field of molecular biology. In reading this article several considerations should be kept in mind. One must realize that "recombinant DNA" technology (or "gene splicing" or "DNA cloning") represents a collection of methodologies that provides a very powerful research tool for many areas of biology and medicine. These methodologies range from microbial genetics and enzymology to the chemical synthesis of DNA and the determination of nucleotide sequences of DNA. To simplify, this technology provides the wherewithal to manipulate, identify and purify segments of DNA from any organism and produce them in substantial quantity for analysis and investigative purposes. In addition, these are the core methodologies for the modern biotechnologic industry, which focuses on the production of useful and commercially viable biological materials or by-products.

In the past ten years since the "recombinant DNA" or "gene splicing" technology was first developed, significant improvements have continually enhanced the efficiency and resolution of molecular biological research. As a result the numerous achievements documented herein include some truly revolutionary discoveries in biology made in the past few years. The discovery of introns in the genes of higher organisms, the documentation of in vivo somatic recombination events as the mechanism for generating antibody diversity, the elucidation of the molecular basis of genetic diseases and the uncovering of a library of oncogenes are but a few examples. One can certainly anticipate further elucidation and understanding of the biological significance of these and other findings. It is equally clear that several other areas of biological interest will be affected by research based on these methodologies. Of particular interest to the medical community will be the thrust into the molecular biological mechanisms of the immune system, and the mysteries of neurobiology and mammalian development.

Notwithstanding the remarkable discoveries made in the past decade, one could ask how many patients have directly benefited from this research. The number must be small. Human insulin is not widely marketed, and only a small number of patients have been treated in clinical trials with the handful of biologicals developed in the biotechnologic industry. Nevertheless, as evidenced in the Specialty Conference in this issue, enthusiasm is widespread in the expectation for significant medical contributions at the patient level. The reason for the delay in direct patient benefits can be illustrated by considering the differences between basic research and the development of a biological product based on the results of basic research. The significant advances in basic research made to date derive from experiments designed to answer questions about biological mechanisms, which in turn generate intellectual constructs. In providing diagnostics or biological materials for the treatment of diseases or genetic disorders, one must first rely on the intellectual constructs as the basis for developing a useful product. The biotechnologists design and engineer an organism that synthesizes the product, and then large-scale production and purification systems must be developed. These processes must be carefully monitored to provide a quality-controlled product. Preclinical data must be gathered to obtain permission to conduct clinical trials. Clinical trials are very expensive and require long trial periods and very long review periods before a final decision is made. So, in addition to a substantial research effort, an even more substantial developmental effort (in terms of qualified personnel, facilities and financial support) must be put forth before a biological product can be made available to the patient population. The research and development of a genetically engineered microbe for the production of a particular biological product is not the limiting factor in bringing the promise of modern biology to medicine and humanity. The time and capital-intensive elements required for the development of the large-scale processes and the regulatory pathway account for the delay in the delivery of useful products to the medical patient population. Of course, this long development time is obvious to those with any knowledge of the pharmaceutical drug industry, but the neophyte biotechnologists have had to experience this baptism.

The rapid pace of exciting biological research, with much of it related to medicine, should continue for at least another decade. Medically useful biologicals and other products derived from this basic research will flow through the developmental trenches and trickle through the regulatory pipeline to the needs of the public. This latter remark is not to be construed as criticism of the regulatory mechanism but rather as a statement of fact. One must take comfort in the fact that the safety and best interests of the public are paramount through all phases of the developmental and regulatory processes. For scientists seeking the excitement of understanding and for the public looking for new medical treatments, these are very promising times.

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